

REMARKS

The following issues are outstanding in the pending application:

- Claims 3-8, 10-11 and 14 are rejected under 35 USC § 103; and
- Claims 3-8, 10-11 and 14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting.

Claim Amendments

Claim 14 has been amended to more clearly define the subject invention. Claim 14 now recites a method of animal weight maintenance that includes the steps of 1) simultaneously providing said animal an excess quantity of a multi-component foodstuff, the foodstuff comprising two or more compartmentalised food compositions, wherein at least two of the compositions differ from each other by at least 1% on an energy ratio basis in their content of two or more of fat, protein and carbohydrate, in which the food compositions comprise 50 to 75% fat on a fat:energy ration basis, 50 to 75% protein on a protein:energy ratio basis and 26 to 50% carbohydrate on a carbohydrate:energy ration basis; 2) allowing said animal to freely self-select from the excess quantity of the compartmentalised food compositions; and wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs in order to maintain the animal's weight. Support for this amendment is found in paragraphs [0016]-[0018] and [0024] of the specification. No new matter has been added.

35 USC § 103

Claims 3-8, 10-11 and 14 are rejected under 35 USC § 103(a) as having subject matter unpatentable over WO 01/97630 in view of U.S. Pat. 6,410,063 to Jewell et al., and further in view of Romsos et al. (JAVMA vol. 182(1), pp 41-43 1983); Wills, Josephine ("Adult Maintenance", BSAVA Manual of Companion Animal Nutrition & Feeding, Chap. 3, pages 44-46, 1996); Rice ("The Dog Handbook", pages 48-49); and JP 02238464. Applicant respectfully traverses this rejection.

WO 01/97630 is directed to a dietary regime for companion animals in which one pet food product is fed as the morning meal and a second pet food product is fed as the afternoon/evening meal. The morning meal has a higher protein content than the afternoon/evening meal and the afternoon/evening meal has a higher fat content than the morning meal. The fat content of the afternoon/evening food should be higher than the fat content of the morning food by at least 5 % of the total calorie content of the food. The calories contributed by the fat content of the food for the morning should be between 20 % and 70 % of the total calorie content of the food and the fat content of the food for the afternoon/evening should contribute between 25 % and 75 % of the total calorie content of the food.

Jewell discloses a method for inducing a state of ketosis in a canine by means of dietary manipulation. The method comprises feeding to a canine in need of such ketosis, on a regular basis, a diet of a single pet food that includes carbohydrate measured as nitrogen free extract of about 0 to about 20 wt. %, protein of about 25 to about 70 wt. %, and fat of about 20 wt. % to about 70 wt. %. The diet is essentially a high fat, low carbohydrate diet that results in the attainment of a ketonic state (Col. 5, lines 12-13).

Romsos describes a study that was done to determine if dogs are able to regulate protein intake independently of energy intake, as it is known that dogs are able to regulate their intake of energy. It was found that by allowing dogs access to 2 diets that differed in protein and by rotating the position of each diet within the cage, the dogs were able to adjust their feeding pattern to maintain a constant protein intake without affecting energy intake. The findings of the experiments determine that palatability alters the protein selection in adult dogs. However, Romsos states that because the concentration of fat in the diet affects the self-selected protein, the fat to carbohydrate ratio was also varied in the 2 lower-protein diets. Romsos only looked at the effect of protein on energy intake and did not vary the amount of carbohydrate and fat (other than to compensate for the varying protein levels). Romsos thus states that it is possible that a ratio of dietary fat to carbohydrate wider than that used in the study would effect protein intake in dogs.

The Wills referenced is directed to the general nutrient requirements of dogs and cats in which the composition of a balanced diet and factors affecting food intake are discussed. In the section discussing the feeding regimen for dogs, Wills states that dogs have a good enough appetite to eat all they require in one meal per day and that it is satisfactory to adopt a once-a-day feeding regimen. Regarding the feeding regimen for cats, Wills states that: cats reject diets low in protein because such diets are rather unpalatable. Cats also can detect and may reject diets that are deficient in certain nutrients, such as taurine, niacin and vitamin A. In the Willis reference, an owner is supplying the pet with one pet food product per meal.

Rice describes free-choice feeding as “leaving a least a one-day supply of premium dry dog food where it is accessible to Daisy at all times.” Further, “ - - - she should be fed free-choice premium dry puppy food, plus two small daily meals of canned and dry food mixed.” The Rice reference, on page 48 in the second paragraph under the heading “Free-Choice Feeding”, states “free-choice means leaving at least one day’s supply of premium dry dog food where it is accessible to [the dog] at all time”. The teaching of Rice allows the dog to “graze” on one type of foodstuff during the day.

JP 2002238464 is directed to a pet food capable of meeting a pet’s nutritional requirements without the pet losing interest in the daily meal. Two or more kinds of different food materials are stored in individual packaging bodies. The plural packaging bodies, including the food materials, are stored in a single packaging container. The food includes a staple food, such as dry type food, and a side dish which can be different each time it is given. The selection of the food by the cat appears to be based on palatability.

In *KSR*, the U.S. Supreme Court reaffirmed the Graham factors in the determination of obviousness under 35 U.S.C. § 103(a). The four factual inquires enunciated therein for determining obviousness are: (1) determining the scope and contents of the prior art; (2) ascertaining the differences between the prior art and the claims in issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating evidence of secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), *KSR Int’l Co. v. Teleflex Inc.* 127 S. Ct. 1727, 1734-35, 167 L. Ed. 2d 705, 715 (U.S. 2007).

In this case, neither the level of ordinary skill in the art, nor secondary considerations are at issue. However, in order to assess the scope and content of the prior art properly, a thorough understanding of the invention must be acquired by studying Applicant's claims and the specification. M.P.E.P. § 2141. Thus, the inquiry begins with construction of Applicant's claims, explained below. Next, when ascertaining the differences between the prior art and the claims at issue, both the invention and the prior art references as a whole must be considered, and *all* claim limitations must be considered when determining patentability of Applicant's invention. M.P.E.P. §§ 2141; 2143. When this is properly done in this case, as shown below, it becomes clear that differences exist that preclude obviousness. And finally, the test for obviousness requires identification of a reasonable basis for combining the claimed elements in the claimed fashion. *KSR*, 127 S. Ct. at 1741; M.P.E.P. §2143. As shown below, this requirement is not met in this case, and no *prima facie* case for obviousness is made.

Applying the proper test to this case begins with amended independent claim 14 directed to a method for animal weight maintenance that includes the steps of 1) simultaneously providing the animal an excess quantity of a multi-component foodstuff, the foodstuff comprising two or more compartmentalised food compositions, wherein at least two of the compositions differ from each other by at least 1% on an energy ratio basis in their content of two or more of fat, protein and carbohydrate, in which the food compositions comprise 50 to 75% fat on a fat:energy ration basis, 50 to 75% protein on a protein:energy ratio basis and 26 to 50% carbohydrate on a carbohydrate:energy ration basis; 2) allowing the animal to freely self-select from the excess quantity of the compartmentalised food compositions and 3) wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs in order to maintain an animal's weight.

The prior art does not teach a method for animal weight maintenance that includes at least the steps of 1) simultaneously providing the animal an excess quantity of a multi-component foodstuff, in which the foodstuff comprises two or more compartmentalised food compositions; 2) allowing the animal to freely self-select from the excess quantity of the compartmentalised food compositions; and wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs in order to

maintain the animal's weight. The WO '630 application teaches a pet food diet in which a single pet food product is fed twice a day wherein one product contains 20-70% fat and the other pet food product contains 25-75% fat in which the animal prefers a composition having a different fat content in the morning than in the evening. It does not teach allowing the animal access to an excess quantity of the pet food product, nor does it teach anything related to weight maintenance by simultaneously providing an animal with an excess quantity of different food compositions. Jewell discloses a method for inducing a state of ketosis in a canine by means of dietary manipulation in which a single pet food product is fed a dog that is essentially a high fat, low carbohydrate diet that results in the attainment of a ketonic state. However, when combined with WO 01/97630, neither of these references teach feeding excess quantities of the food compositions in which at least two of the compositions differ from each other by at least 1% on an energy ratio basis in their content of two or more of fat, protein and carbohydrate, wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs in order to maintain the animal's weight.

Romsos also does not cure the deficiencies in the WO '630 and Jewell applications. The experiments in Romsos involve giving dogs diets with various protein concentrations. The findings of the experiments determined that palatability alters the protein selection in adult dogs. The method of claim 14 is directed to weight maintenance in an animal, not with palatability and in fact, the subject application illustrates the opposite; that palatability is overridden by the macronutrient requirement of the animal and therefore the animal will self-select based on the macronutrient content of the foodstuff. The test data in the specification shows that palatability does not affect the macronutrient ratio selection by the animal. Furthermore, Romsos only looked at the effect of protein on energy intake and did not vary the amount of carbohydrate and fat (other than to compensate for the varying protein levels). Therefore, the animals were not able to vary each macronutrient independently from an excess quantity of food components, which means they were not able to meet the optimum macronutrient ratio for their metabolic needs in order to maintain the animal's weight. The surprising effect of the present invention is that animals are able to self select to not only to reach their optimum macronutrient ratio, but to also achieve their required caloric intake without eating to excess, which results in weight gain.

The Examiner further states that because Wills teaches that cats can detect nutritional deficiencies in their diet, animals would be capable of self-regulating their diets based on optimal macronutrient content, which would be expected to be protein because cats and dogs are carnivorous. In Wills, the low protein diets are rejected by cats because they are unpalatable, not because they do not have an optimal macronutrient content. There is nothing in Wills that suggests that animals are capable of self-regulating their diets when offered an excess quantity of food. Examiner has stated that Rice shows that “free-choice” feeding of dogs is a known method of feeding dogs to prevent obesity or overeating. However, the Rice reference teaches that “free-choice means leaving at least one day’s supply of premium dry dog food where it is accessible to [the dog] at all times”. The teaching of Rice allows the dog to “graze” on one type of foodstuff. It does not teach allowing an animal to self-select from an excess quantity of different types of foodstuff to achieve its target macronutrient ration for it’s metabolic needs at that time while at the same time maintaining the animal weight. The JP patent is related to packaging of a variety of pet foods in which the cats chose the food based on palatability.

In order to make a proper *prima facie* case for obviousness, all claim limitations must be accounted for. M.P.E.P. § 2143.03. This rejection fails to consider all elements of the claims and their meaning as the cited references do not include all elements of independent claim 14. This is because the combination of references does not teach a method of animal weight maintenance that includes at least the steps of 1) simultaneously providing an animal an excess quantity of a multi-component foodstuff, 2) allowing the animal to freely self-select from the excess quantity of the compartmentalised food compositions; wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal’s metabolic needs in order to maintain an animal’s weight.

Applicant respectfully submits that the disclosure in the JP patent of an animal having the ability to select the optimal type of food for itself, with offering a variety of different types of food already being practice in the art, taken with the above references that also show a concept of a variety of foods be offered would not make it obvious to provide for method of animal weight maintenance as recited in amended independent claim 14. As discussed above, the combination of these references does not provide for simultaneously providing an

animal an excess quantity of a multi-component foodstuff, allowing the animal to freely self-select from the excess quantity of the compartmentalised food compositions, wherein the driver for the self-selection is based upon a target optimum macronutrient ratio for the animal's metabolic needs in order to maintain the animal's weight. Therefore, Applicant respectfully submits that independent amended claim 14 is not obvious.

If an independent claim is non-obvious under 35 U.S.C. 103, than any claim depending therefrom is by definition non-obvious. Applicant respectfully submits that claims 3-8, 10 and 11 depend at least in part from amended independent claim 14. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 3-8, 10, 11, and 14 under 35 U.S.C. 103(a) as having subject matter unpatentable over WO 01/97630 in view of U.S. Pat. 6,410,063 to Jewell et al., and further in view of Romsos et al. (JAVMA vol. 182(1), pp 41-43 1983); Wills, Josephine ("Adult Maintenance", BSAVA Manual of Companion Animal Nutrition & Feeding, Chap. 3, pages 44-46, 1996); Rice ("The Dog Handbook", pages 48-49); and JP 02238464.

Double Patenting

The claims have been rejected for obviousness-type double patenting in view of claims 1-15 of 10/742360. No patent has issued yet from U.S. Patent Application No. 10/742360, thus a rejection on the basis of double patenting is premature and Applicants treat it as a *provisional* rejection on the stated basis. Provisional double patenting rejections of this type do not require Applicants' to act at this time. The Court of Claims and Patent Appeals (now the Court of Appeals for the Federal Circuit) has stated, "Once the provisional rejection has been made, there is nothing the examiner and the applicant must do until the other application issues." *In re Mott*, 190 U.S.P.Q. 536, 541 (C.C.P.A. 1976). In fact, Applicant respectfully submit that the amendments made herein above render the current double patenting rejection moot. M.P.E.P. section 804 allows for the prosecution to continue while a provisional double-patenting rejection is pending and even instructs the Office to continue to make such a provisional rejection until one of the applications issues as a patent. Thus, the rejection is noted, and Applicants' will address the rejection appropriately once one of the asserted conflicting claim sets has been deemed allowable.

CONCLUSION

Applicants believe the above addresses all outstanding issues and the Application is now in condition for allowance.

The fee for a three month extension of time is being submitted with this response. If additional fees are due, please charge our Deposit Account No. 06-2375, under Order No. HO-P03188US0, from which the undersigned is authorized to draw.

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Respectfully submitted,

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